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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,400

02/02/2007

Zoser B. Salama

7014-110

8658

46002 7590 12/24/2008

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EXAMINER

NAZARIO GONZALEZ, PORFIRIO

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

12/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,400	Applicant(s) SALAMA, ZOSER B.	
	Examiner PORFIRIO NAZARIO GONZALEZ	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-9 and 11-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2, 6-9 and 11-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Response to Arguments***

Applicant's arguments filed 8/14/2008 traversing the rejection of claim 1 under 35 U.S.C. 112, second paragraph are found persuasive and therefore said rejection is withdrawn by the Examiner.

However, Applicant's arguments traversing the rejection of claims 2, 6-9, 15 and 16 under 35 U.S.C. 112, second paragraph have been fully considered but they are not persuasive. Applicants make the observation that there is no indication in the specification that the shown compound in claim 2 should be neutral. Further, Applicants argued that while the formula of claim 2 is neutral, one skilled in the art would expect a charge at the positions X_1 and X_2 when both or either one is magnesium or calcium. The Examiner does not disagree with Applicants assertion that when positions X_1 and X_2 are both or either one is magnesium or calcium, the formula of claim 1 is no longer a neutral compound but rather a cationic organometallic complex. The issue here is that the formula presented does not provide for that fact. The formula shown only embraces neutral compounds when X_1 and/or X_2 are Na^+ , K^+ , Li^+ , alkyl or aryl residues. There is no language and/or graphical representation in the claim that would account for a cationic complex. The Examiner can only interpret the claim, based on the general formula shown, that Applicants intended to claim a neutral platinum compound that embraces the formula depicted in claim 2. Note that if applicants intended to claim the cationic platinum complex as well as the neutral complex then the corresponding language and/or graphical representation of the total charge of the complex should be part of the general formula. The formula as shown runs contrary to standard nomenclature in the art when depicting cationic metal complexes. Thus, the claims are not clear and the rejection of the claims is sustained.

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Applicants' argument for traversing the rejection of claims 11-14 under 35 U.S.C. 112, first paragraph with respect to the use of treatment of cancer tumors as a model for the treatment of other diseases which are expressed by cell proliferation is well taken and as such, the rejection with respect to treatment is withdrawn by the Examiner.

However, Applicants' argument traversing the rejection of the claims 11-14 under 35 U.S.C. 112, first paragraph with respect to the use of the compound of claim 2 for prophylaxis has been considered but is not persuasive. Applicants' argued that a person skilled in the art (here it's a doctor or a medical scientist) would know how to administer the medication as a preventive treatment (prophylaxis) of cell proliferation (in this case cancer) based on the medical history of the patient and his/her family. The Examiner respectfully disagrees. Basler and Groettrup, *Drug Aging*, Vol 24, no. 3, pp. 197-221 (2007) have concluded that in the case of prostate cancer, especially metastatic prostate cancer, the development of new breakthrough treatment options in tumour vaccination have not been achieved. Furthermore, most of the current strategies are limited to a palliative role. None of the current treatments prevents (prophylaxis) metastatic prostate cancer. Shore et al., *Aliment Pharmacol Ther*, Vol. 18, pp. 1049-1069 (2003) notes that the only treatment that cures pancreatic cancer is surgery. Chemotherapies have only shown to prolong survival of patients having pancreatic cancer. None of the chemotherapies prevents pancreatic cancer. Boulikas et al., *Oncology Reports*, Vol. 10, pp 1663-1682 (2003), reviews the last 20 years of platinum drugs for the use in cancer treatment. The review article only mentions the use of these platinum compounds as treatment of cancer and not as a preventive drug. It is clear that at the present time none of the platinum drugs available are use in the prevention (or prophylaxis) of cancer. Further, all of the platinum complexes used as anti-cancer drugs are not view as part of the strategies currently in development in the area of tumor vaccination. One skilled in the art will logically conclude that

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platinum drugs are well suited for treatment of cancer but that there is no evidence that such drugs can be use for the prevention of cancer. Therefore, one skilled in the art lacking the knowledge of how to prevent cancer with the platinum drugs would not be able, without undue experimentation to practice the claimed invention. Thus, the rejection of claims 11-14 and new claim 17 under 35 U.S.C. 112, first paragraph with respect to the use of the compound of claim 2 for prophylaxis is sustained. Note that "inhibiting" is synonymous with prevention and thus is the same as prophylaxis.

Allowable Subject Matter

Claim 1 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PORFIRIO NAZARIO GONZALEZ whose telephone number is (571)272-0641. The examiner can normally be reached on M-F (9:30 A.M.-6:00 P.M.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/PORFIRIO NAZARIO GONZALEZ/
Primary Examiner, Art Unit 1621

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December 21, 2008